PERFORM Centre

PERFORM Operating Document

Use and Cleaning Procedures for Ambulo™ 2400

PC-POD-CP-011-v01

Revision History

Version	Reason for Revision	Date
01	New POD	March/31/2016

Summary

The content of this POD provides guidelines for the safe use and cleaning of the Ambulo™ 2400 as identified as equipment inventory at the PERFORM Center, Concordia University.

PERFORM Centre

Table of Contents

PERFORM Centre

1 Definition of Terms

Standard operating procedure (SOP)	SOP's at PERFORM are any operating document that require a full review process and approval by the scientific director.
PERFORM operating document (POD)	Operating documents that are specific to an instrument or technique that require approval by area managers.
User	Person using space or equipment at the PERFORM Centre that has received adequate technical and safety training.
Area manager	Person responsible for all activities in a given area of PERFORM such as the athletic therapy clinic, clinical analysis laboratories, conditioning floor, etc.
Supervisor, Cardio-Pulmonary Suite	Person responsible for coordinating the research, community, and teaching activities in the Cardio-Pulmonary Suite.

2 Relevant Documents

This POD is governed by the following Concordia University policies, SOPs, and PODs:

- Ambulo™ 2400 User Manual.
- PC-SOP-GA-007 "General Access to PERFORM Centre".
- PC-SOP-GA-009 "Emergency Response Procedures at the PERFORM Centre".
- PC-SOP-GA-011 "Guidelines for Management of Incidental Findings at PERFORM".
- PC-POD-GA-001 "PERFORM Centre Booking System for Facilities and Equipment".

3 Introduction

3.1 Background

The Ambulo™ 2400 is a compact, non-invasive Ambulatory Blood Pressure Monitoring (ABPM) system. Once installed by a physician or other health professional, the ABPM technology can be used to automatically measure systolic/diastolic blood pressure and heart rate over an extended period of time without medical supervision – typically 24 hours. Once the measurements are complete, they can be downloaded to a computer for analysis and interpretation.

3.2 Purpose

The objectives of the current POD, are to 1) outline the procedure of using the Ambulo™ 2400; 2) provide a set of standard practices for the safe operation and training guide for new users of the systems at the PERFORM Centre, Concordia University; and 3) outline the procedure of cleaning/disinfecting as well as general maintenance of the device, cuffs and tubing.

3.3 Scope

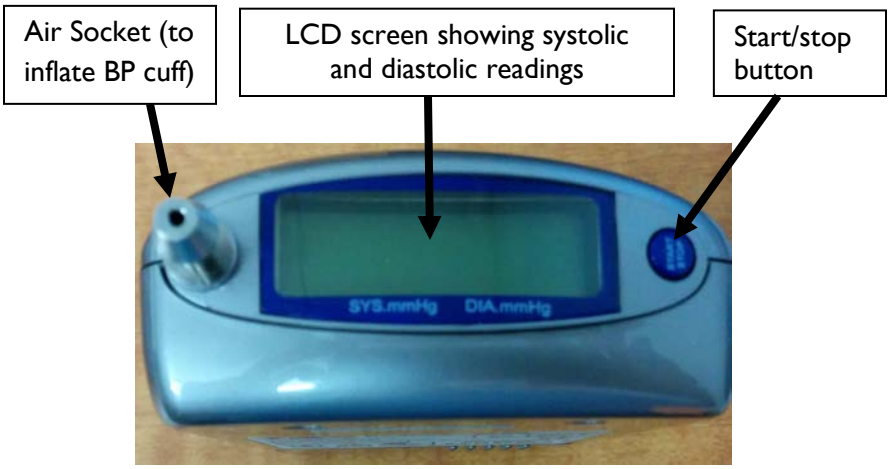
This POD applies to all users and supervisors using the Ambulo™ 2400 at the PERFORM Centre, Concordia University. Any other document other than this POD is out of scope for this operating procedure.

3.4 Responsibility

It is the responsibility of all users and supervisors to ensure that this POD is followed.

4 Main Components of the Ambulo™ 2400

4.1 Ambulo 2400 ABPM Device – Portable automatic systolic/diastolic blood pressure machine.



The following are the general instructions for the start/stop button:

- If pressed once, a manual pressure measurement will be taken.
- If pressed during a pressure measurement, it will immediately stop the measurement and deflate the cuff.
- Hold for 3 seconds to initiate PAUSE mode. Can be used if the participant does not want measurements taken (e.g. bathing or changing clothes). To get out of PAUSE mode, click and hold the start/stop button for 3 seconds.
- To reset the Ambulo™ 2400 press and release the button 3 consecutive times.

NOTE: This button can be disabled by the health professional during user configuration via the software setup. In this case, manual measurements will not be

controlled by the user. The user will still be able to stop a measurement in progress by pressing the button.

4.2 Carrying Pouch with Belt Clip – encases and secures Ambulo™ 2400.

4.3 Extension Hose – provides longer tubing from Ambulo™ 2400 for blood pressure (BP) cuff when using shoulder strap method.

4.4 Easy Wear™ Cuff – encases Ambulo 2400™ around arm.

4.5 Shoulder Strap – provides optional method for carrying Ambulo™ 2400.

4.6 USB Cable – Connects Ambulo™ 2400 to computer.

4.7 Blood Pressure Cuffs – Includes two regular sized adult cuffs, two large sized adult cuffs, one small sized adult cuff, and one child sized cuff.

PERFORM Centre

(Example of a regular adult BP cuff)

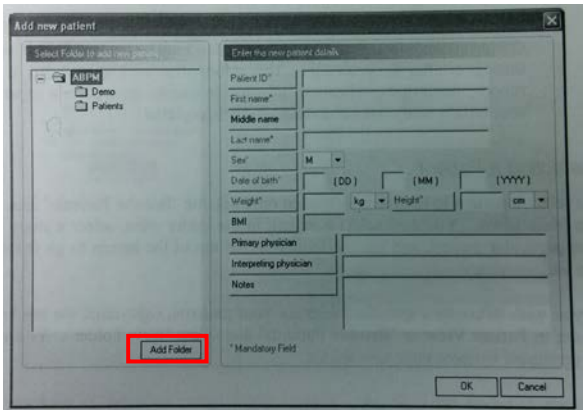
5 Configurations

5.1 ***Starting the Program***

5.1.1 Click on the "Hypertension Diagnostics Suite" (HDS) program icon on desktop OR click the start menu → Programs →Tiba Medical → Click "HDS".

5.2 ***Entering Participant Information***

5.2.1 Create a new participant.
5.2.2 Click on "New patients" icon.
5.2.3 On the left hand side of screen, select "ABPM" folder and click "Add Folder".
5.2.4 Fill in required fields in pop up.
5.2.5 Click "OK".
5.2.6 Fill in required fields (in red) on right hand side of screen.
5.2.7 Click "OK".



5.3 ***Select an existing participant***

5.3.1 Click on "Browse patients".
5.3.2 Perform one of the following:
5.3.2.1 Select a participant in the folder view.
5.3.2.2 Select a study for that particular participant.
5.3.2.3 Use the toolbar (top of screen) to change views.

5.4 ***Edit or Delete an Existing Participant***

5.4.1 Click on "Browse patients".
5.4.2 Select participant. Click "Edit" or click on "Delete patient" icon (garbage can).

NOTE: You must be logged in as an administrator or a Standard User to edit or delete participants.

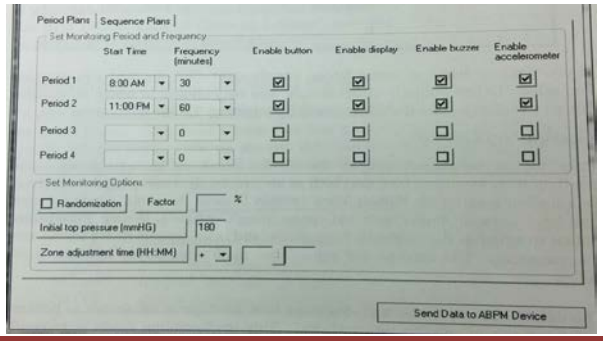
5.5 ***Configurations – Period Plans for a Participant***

This option is designed for easy adjustment of waking and sleep periods to match the participants sleep habits. In this section, start times and frequency of measurements can be identified as well as options selected.

NOTE: For general configurations complete Period Plan section, however, if specific configurations are required complete the Sequence Plans section. Hence only one section needs to be completed.

5.5.1 Click on "Configure device" icon.
5.5.2 Select participant folder.
5.5.3 Click "Configure device parameters".
5.5.4 Configuration options are as follows:

- *Start Time*: When the measurement period will begin.
  NOTE: Periods must be consecutive.
- *Frequency*: The frequency of measurements starting at that time period.
- *Enable Button*: If enabled (i.e., checked), the participant will be allowed to take manual measurements by pressing the "Start/Stop" button. If disabled (i.e., unchecked), the participant will only have the ability to stop a measurement in progress, or enter PAUSE mode by holding the "Start/Stop" button for 3 seconds.
- *Enable Display*: If enabled, blood pressure and heart rate will be displayed on the screen. If disabled, the screen will only display time and time until next measurement.
- *Enable Buzzer*: When enabled, the ABPM will beep 1 minute prior to a measurement, during the deflation process, and when the measurement is complete. This helps remind the participant to avoid arm movement.
- *Enable Accelerometer*: When enabled, this helps track movement, which can identify sleep/wake cycles during a 24 hour period.
- *Randomization*: Measurements will fluctuate around a defined frequency interval when predictable measurements are not desired. The percentage inputted will relate to the amount of randomized measurements that will take place (i.e., higher percentage means a higher number of measurements will be randomized).
- *Initial Top Pressure*: Usually set to 180 mmHg.
  NOTE: For hypertensive individuals, the top pressure number should be higher than 180. For hypotensive individuals, it should be lower than 180.
  NOTE: Setting the top pressure too low can lead to inaccurate readings of the systolic blood pressure.
- *Zone Adjustment Time*: If the participant will be travelling outside of the current time zone, the time on the ABPM can be changed accordingly.
- Click "Send Data to ABPM Device".



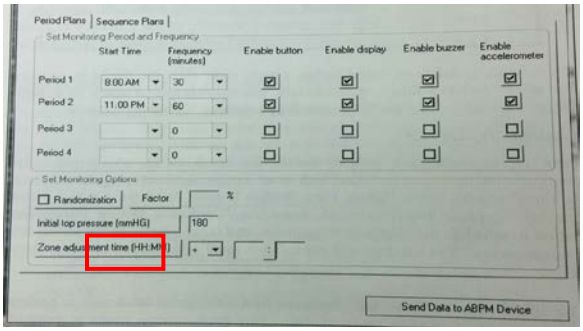
5.6 ***Configurations – Sequence Plans for a Participant***

Frequency plans can be setup to make specifications within each period.

5.6.1 To take measurements at specified intervals, select the "Sequence Plans" tab.

NOTE: The Sequential mode uses up to 4 periods. The first sequence period begins when the start/stop button is pressed (trigger event).

NOTE: When the delays and measurement from the first period have been completed, the second period will automatically begin. The configured sequence continues in this fashion until all periods have been completed.



5.6.2 To modify a period configuration, do the following:

5.6.2.1 Click the configuration to be modified (under description) on the right.

5.6.2.2 Make changes to the setting on the left. Options are the following:

5.6.2.2.1 Accelerometer: Tracks actigraphy data (movement); Assists the software in determining/displaying asleep and awake times. Available settings are ON or OFF.

5.6.2.2.2 Button: "Abort and Pause" ensures the participant has the ability to stop a measurement in progress by pressing the Start/Stop button or activating pause mode to halt a measurement, "Abort only" ensures the participant has the ability to stop a measurement in progress by pressing the Start/Stop button, "Ad-Hoc" initiates a

measurement manually if none is active, "All" activates all options above.

5.6.2.2.3 Buzzer: If enabled, the Ambulo 2400™ will beep one minute prior to a BP measurement, during deflation, and after the measurement is complete.

5.6.2.2.4 Display: Select displayed information from the drop-down list including "12 Hour", "12 Hour, Countdown", 12 Hour, Results", "12 Hour, Countdown and Results", "12 Hour, pressure", "12 Hour pressure and countdown", "12 Hour Pressure and Results", "12 Hour, All", "24 Hour", "24 Hour, Countdown", 24 Hour, Results", "24 Hour, Countdown and Results", "24 Hour, pressure", "24 Hour pressure and countdown", "24 Hour Pressure and Results", "24 Hour, All".

5.6.2.2.5 Result Duration: Controls the number of seconds the result of a BP measurement is shown on the screen by choosing a value from the drop-down list or typing it in manually.

NOTE: The "Results" option from the "Display" list must be inputted first or else this function will not appear.

NOTE: Choosing a long duration may cause some of the measurements to be missed as a BP measurement cannot be taken while the results are being displayed.

5.6.2.2.6 Retry: If enabled, another BP measurement will begin if there is an error that prevents a reading from occurring.

5.6.2.3 Click the "Change" button.

5.6.3 Instead of defining periods and should continuous and consistent measurements be desired, precisions can be made regarding delay, number of measurements, and amount of time between measurements in the "Measurement Entry" box.

5.6.4 To add a new period configuration on the right hand side, do the following:

5.6.4.1 Click the measurement group on the right hand side.

5.6.4.2 Input the desired settings on the left hand side.

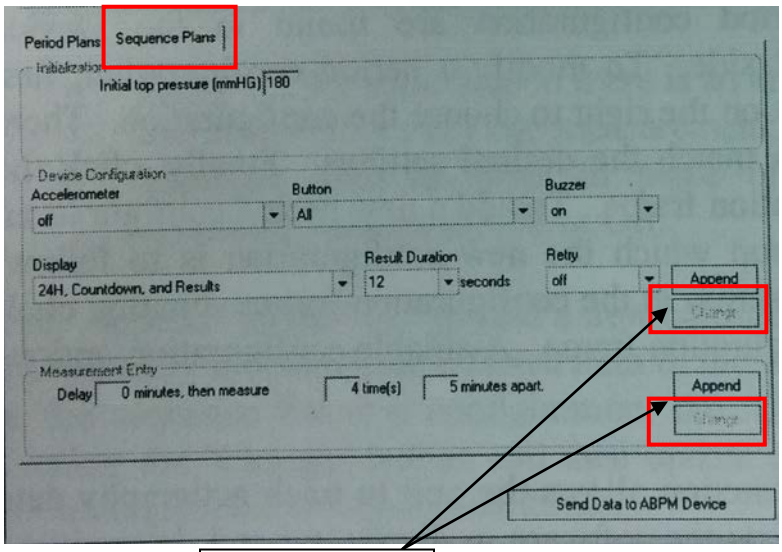
5.6.4.3 Click "Append".

PERFORM Centre

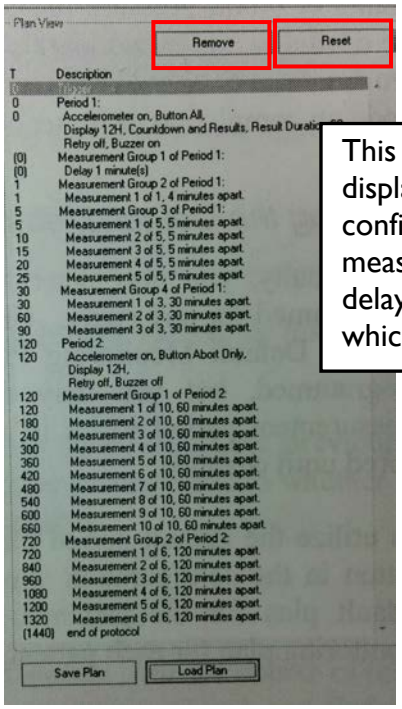
5.6.5 A measurement group can be removed or reset by doing the following:

5.6.5.1 Select the measurement group of interest.

5.6.5.2 Click "Remove" to delete the selected period or "Reset" to clear and reset all the information of that sequence plan.



Change button



This sequence list displays the current configuration periods, measurements, and delays in the order in which they will occur

NOTE: The maximum number of measurements per measurement group is 9999, and the max amount of measurement groups per configuration period is 20.

NOTE: The batteries may not be able to last for a very high number of BP measurements and measurement groups.

5.6.6 Click "Save Plan".

5.6.7 A previous sequence plan can be used by pressing the "Load Plan" button.

5.6.8 Connect Ambulo 2400™ to computer via USB cable.

5.6.9 Clicking "Send Data to ABPM Device".

5.7 ***Configurations – Period Plans for a Study***

A default period plan can be made to be quickly programmed for any study.

5.7.1 Under the tools tab, click "Define Default Monitoring Plan".
5.7.2 You can use the default plan that comes with the software or create your own default plan.
5.7.3 Once completed, it will be stored until changed.
5.7.4 Click "Ok".
5.7.5 On the left hand side of screen, select a study.
5.7.6 Click on "Configure Device" icon.
5.7.7 Select a participant.
5.7.8 To use the default period plan, click "One Click Device Programming". This will automatically configure the device to the default plan you made.
5.7.9 This will eliminate the need to define a new monitoring plan for each participant.

6 Equipment Setup

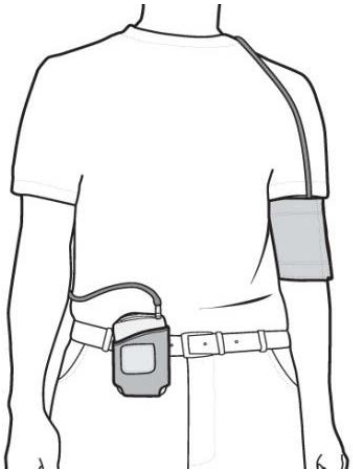
6.1 The participant should wear loose clothing and a short-sleeve shirt or blouse for the procedure.
6.2 Review the ABPM procedure with the participant
6.2.1 Explain the pieces of equipment as well as their functions that the participant will be wearing. Mention to participant "If BP cuff causes extreme discomfort, bruising or a rash, immediately remove BP cuff. It is normal to feel some discomfort while the BP cuff is taking a measurement."
6.2.2 Advise the participant to avoid arm movement when a measurement is taken. It would be ideal if the participant can place their arm on a flat surface. The participant should also avoid tapping or placing any external pressure against the device.
6.3 Select an appropriate sized cuff for the participant. Different sizes are available. Each BP cuff is labelled with a range of the minimum and maximum circumference that can be accommodated by that cuff.

NOTE: Selecting the wrong sized BP cuff can overestimate (too small) or underestimate (too big) the BP measurements.

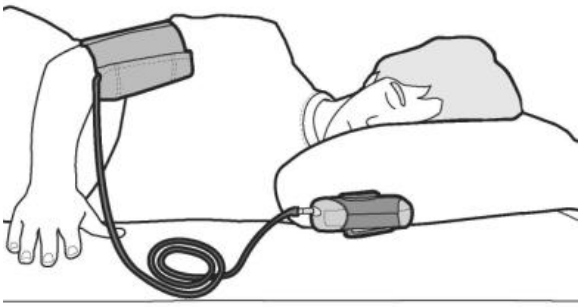
6.4 Place cuff around participant's non-dominant arm (bicep) such that the artery indicator rests on the brachial artery, and the air tube is pointing up towards the participant's shoulders. Allow a finger's worth of slack between the cuff and the arm. The Ambulo™ 2400 can be worn in 4 different ways depending on activity and comfortability:

EasyWear™ Cuff

Shoulder Strap



Belt Clip



Sleeping (Note that the tubing should be at the top of the BP cuff)

EasyWear™ Cuff: An ECG electrode can be placed to the cuff snap and adhered to the participant's skin for additional security to prevent the device from rolling down the participant's arm.

Shoulder Strap or Belt Clip: If the participant would like to use the shoulder strap or belt clip method, connect the extension hose to the tubbing of the BP cuff, run the extension hose behind the participants

back and avoid any excessive slack in the tubing, plug the extension hose into the Ambulo™ 2400 air socket. For the shoulder strap, the device can be worn on the same or opposite side of the cuffed arm.

NOTE: Make sure there is enough slack so the participant can go about his daily activities. If the extension hose is causing too much slack, it can be coiled together and secured to the ABPM device. When coiled, avoid kinking or crimping the hose as this will cause the device to malfunction and/or potentially harm the participant.

7 Taking a Measurement

7.1 ***Participant Instructions***

7.1.1 Review the "Patient Instruction Sheet" (see Appendix I) with participant.

7.1.2 Complete the top section of the "Patient Diary" form, if necessary.

NOTE: This form contains relevant diagnostic information and the participant can make any written remarks in the diary.

7.2 ***Baseline Measurement***

The first measurement is the baseline measurement and must be performed by the health care professional.

7.2.1 Press START/STOP button.

7.2.2 The cuff will pump to top pressure and go down to 45 mmHg.

NOTE: If baseline measurement fails, another measurement will be attempted, however the diastolic value will drop down to 27 mmHg.

7.2.3 Once Baseline measurement is identified, the ABPM device will go slightly above the last systolic value and slightly below the last diastolic value.

NOTE: If the ABPM device cannot detect BP, or if participant suspects large shift in BP, pressing the START/STOP button 3 times will make the device go through the baseline procedure again.

7.2.4 The LCD screen of the ABPM device will display the systolic BP, diastolic BP, and heart rate.

7.3 ***Pausing a Measurement***

PAUSE mode should be initiated by the participant if not wearing device or when the 24-hour procedure is finished.

7.3.1 Hold down START/STOP button for 3 seconds.

NOTE: PAUSE mode will help preserve the battery life and avoid faulty measurements when the cuff is not being worn.

8 Downloading and Reviewing Data

When the participant returns post-examination, collect the ABPM system and all other accessories. Make sure that everything has been returned and is functioning properly.

8.1 ***Downloading Data***

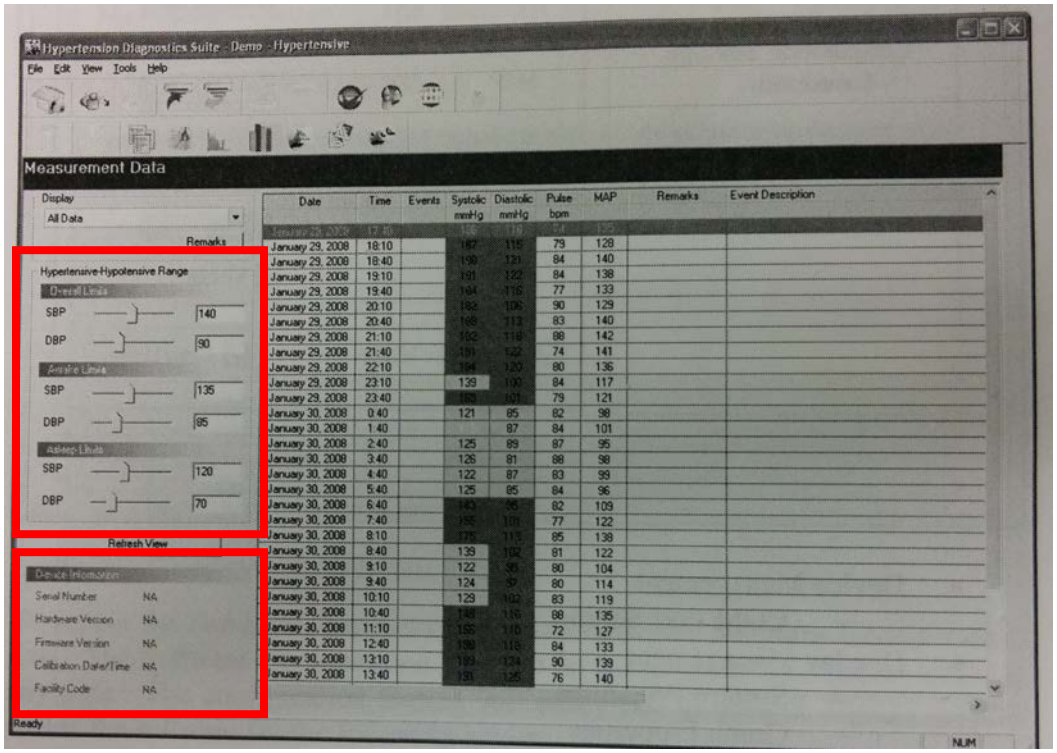
8.1.1 Use the USB cable to connect the ABPM device to the PC.
8.1.2 Click "Hypertension Diagnostic Suite" icon.
8.1.3 Click the "Download Data from Device".
8.1.4 Review the data measurements, and make any necessary changes based upon the Patient Diary form.

8.2 ***Reviewing Data***

Data can be reviewed under various views:

8.2.1 Table View
The Table View is used to expand a study in a spreadsheet format. The raw numbers can be compared side-by-side.

8.2.1.1 Isolation of blood pressure measurements that are above the prescribed limits (seen on left hand side of window) can be done by adjusting the limit bars (Overall, Awake, Asleep) independently.
8.2.1.2 "Device Information" can be seen in the bottom-left of the window (currently showing N/A for all 5 sub-categories; this won't be the case when looking at a real participant's data), which can be used as an audit trail or for troubleshooting purposes.



8.2.1.3 If a measurement appears invalid or erroneous, right-click on the row and select "Exclude Measurement". It will then be displayed in a strikeout font, and will not be included for the statistical or graphical analyses.

8.2.1.4 The software will automatically exclude measurements that are well outside of the expected norms. This occurs during the downloading process of the data measurements. It is turned on by default.

8.2.1.5 The device norms for adults are:

- 8.2.1.5.1 SBP between 70 and 240 mmHg
- 8.2.1.5.2 DBP between 40 and 140 mmHg
- 8.2.1.5.3 Heart Rate between 30 and 125 bpm
- 8.2.1.5.4 Pulse pressures between 40 and 100 mmHg

8.2.1.6 The device norms for pediatrics as well which are the following:

- 8.2.1.6.1 SBP between 60 and 220 mmHg
- 8.2.1.6.2 DBP between 35 and 120 mmHg
- 8.2.1.6.3 Heart Rate between 40 and 180 bpm
- 8.2.1.6.4 Pulse pressure between 40 and 120 mmHg

8.2.1.7 If in any case, you would like to re-include the excluded measurement, right-clicking on the excluded row and select "Include Measurement".

8.2.1.8 Setting Asleep/Awake Time (seen as shading of the rows)

8.2.1.8.1 Found under Actigraphy View button on toolbar.

8.2.1.8.2 Software can automatically calculate it by clicking on the "Calculate Awake/Asleep" button located on the bottom of the Actigraphy View. Ensure that the changes have been made properly.

8.2.1.8.3 To manually find the asleep/awake times, change the ranges under the Actigraphy View button.

8.2.1.8.4 You can also edit the minutes of the asleep/awake times by highlighting the hourly increments with the cursor, and manually entering the values. They will automatically be saved once the changes are made.

8.2.1.9 Range Limits

8.2.1.9.1 The range limits are numbers that can target specific sets of data by changing the color of the numbers on the table.

8.2.1.9.2 Color changes can be seen when the data measurements are either above, below, or within the target ranges. The color scheme is defined from the Software Configuration Menu.

8.2.1.9.3 The range limits are automatically adjusted for pediatric use by the recognition of the participant's birth date.

8.2.1.10 Editing the Range Limits

8.2.1.10.1 Use the sliders on the left side of the table view or input the ranges into the adjacent numeric boxes.

8.2.1.10.2 Asleep and awake limits will change the color of the numbers themselves, and only within the selected time period.

8.2.1.10.3 To accept the changes, click on "Refresh View".

8.2.1.11 Adding Comments to Individual Measurements

8.2.1.11.1 Click on the "Remarks" Section within the appropriate row, and type in your comment.

8.2.1.11.2 Pre-defined comments may be assigned by clicking on the "Remarks" button on the left hand side of the table.

8.2.1.12 Other Table View Options

8.2.1.12.1 To view an hourly mean blood pressure for a participant, or to review a list of error codes as they occurred, use the drop-down menu on the top-left of the Table View window.

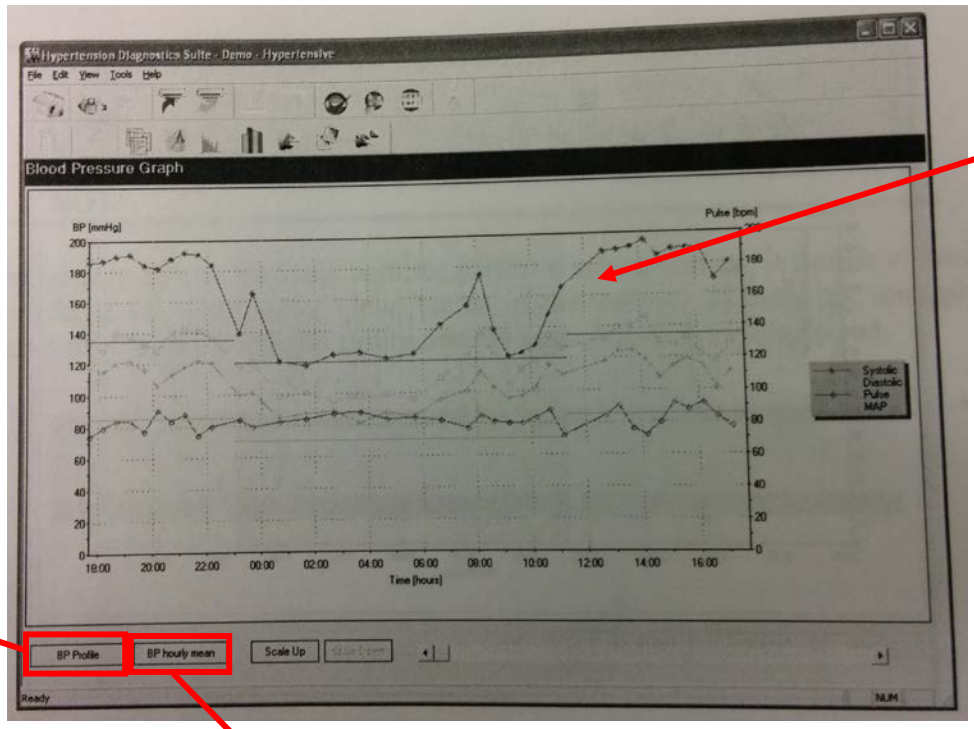
PERFORM Centre

8.2.2 Graphical View

8.2.2.1 Used to view the data measurements plotted within an X and Y-axis diagram.

8.2.2.2 Diagram displays systolic and diastolic blood pressure measurements on the Y axis, and the time of day on the X-axis.

8.2.2.3 The points can either be connected by time or type of measurement (systolic, diastolic), which can be defaulted from the Software Configuration menu.



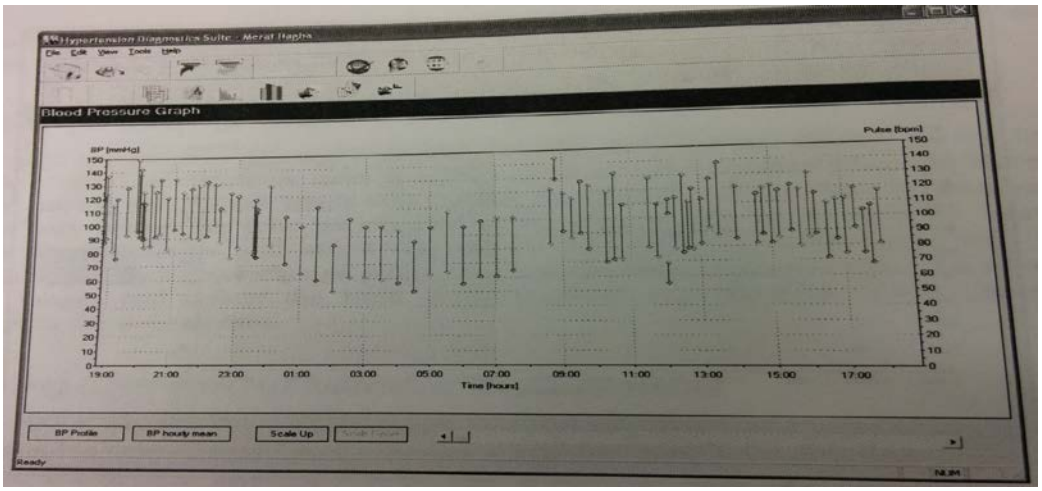
Standard Profile Graph

Shows the standard profile graph (as seen above)

Displays the average hourly BP as a graph

8.2.2.4 Bar Display Option

8.2.2.4.1 Can be applied by selecting "bar display" in the Software Configuration Menu (under Chart View). This will change the graph to a time-based format (example shown below).



8.2.2.5 Diagram or Hide Pulse and Mean Arterial Pressure) MAP Measurements:

8.2.2.5.1 Under "Chart View", you can also choose whether to include pulse and MAP data. The time-based graph above excludes both pulse and MAP, leaving a plot of systolic and diastolic pressures.

8.2.2.6 Scaling Up / Scaling Down / Scrolling:

8.2.2.6.1 The graph will automatically scale down if the data set involves many measurements.

8.2.2.6.2 To zoom in, click on the "Scale Up" button located below the graph.

NOTE: Scaling up will only be applicable if the graph had to initially be collapsed to fit on the screen.

8.2.2.6.3 To scroll across the zoomed data, use the scroll bar below the graph (indicated by an arrow above).

8.2.2.6.4 To zoom out, press the "Scale Down" button.

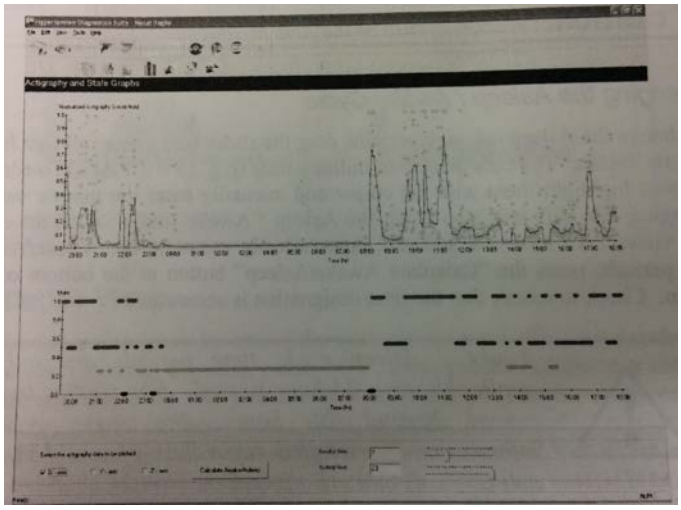
8.2.3 Actigraphy View

8.2.3.1 This view is used to track how much movement the participant exerted throughout the 24-hour measurement period. It is also used to track awake/asleep cycles.

8.2.3.2 It needs to be enabled upon initial participant configuration for the data to be measured.

8.2.3.3 This graph can be viewed by clicking on the "Actigraphy View" button in the toolbar.

8.2.3.4 The X, Y, and Z-axis may be viewed.



8.2.3.5 The Actigraphy algorithm categorizes the level of activity for the participant, using the following color scheme:

Activity Level	Display Color
Daily awake activities, such as walking, working, etc.	Red
Restful activities, including sitting or relaxing	Blue
Idle activities, including sleep	Green
Unit in PAUSE mode (no measurements collected)	Black

NOTE: If the device is in PAUSE mode or if accelerometer data has not been collected during a particular period, the time range will be displayed as idle.

8.2.3.6 Changing the Asleep/Awake Cycle

8.2.3.6.1 Same protocol as in Setting Asleep/Awake Time in Table View.

8.2.3.6.2 The bars displayed military time (e.g. 15 = 3 P.M.)

NOTE: Awake/Asleep cycle time periods are only applicable to a 24-hour period. If the study exceeds 24 hours, it will use the same cycle information regardless of a different asleep/awake pattern beyond the first 24 hours.

8.2.4 Histogram View

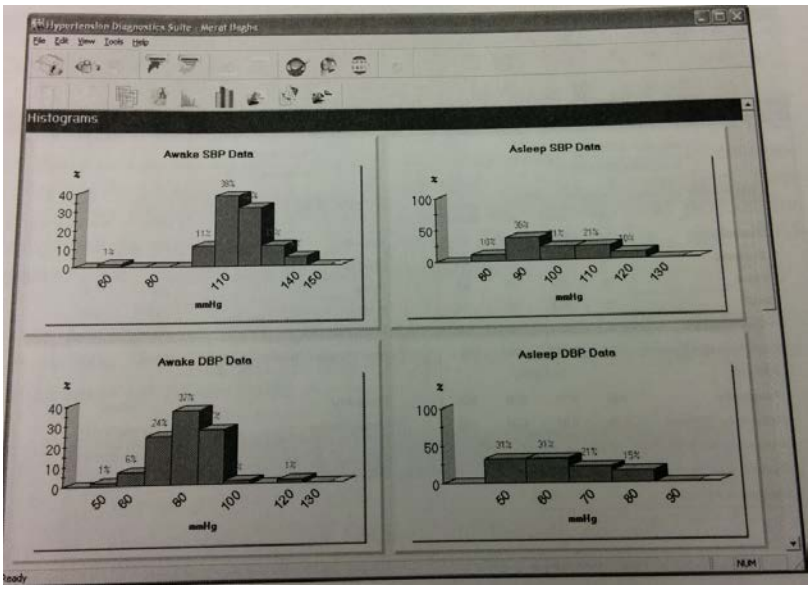
8.2.4.1 Used to view the selected data range into a bar graph.

8.2.4.2 Represents the distribution of the systolic, diastolic, and pulse measurements as a percentage (%) of the total measurements, and is divided into four distinct data sets:

- Systolic (Awake)
- Systolic (Asleep)
- Diastolic (Awake)
- Diastolic (Asleep)

8.2.4.3 The Y-axis represents the percentage of total measurements for that time period, and the X-axis represents the pressure value in mmHg.

8.2.4.4 Useful for tracking trends in BP measurements throughout the 24 hour period.



8.2.5 Statistics View

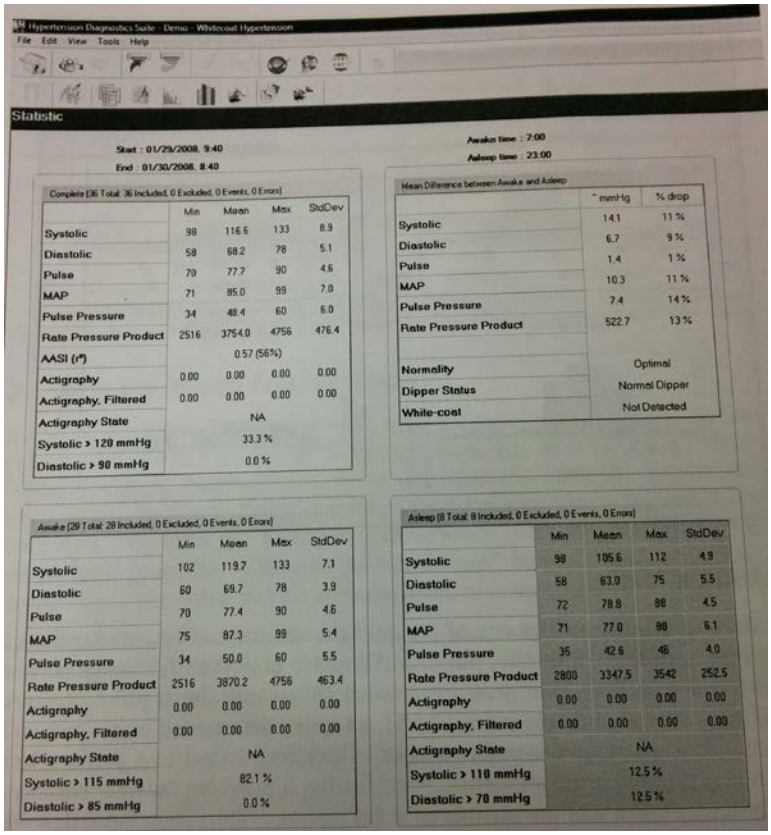
8.2.5.1 Can view the most effective snapshots of the following measurements:

- Systolic and Diastolic BP
- Pulse (heart rate)
- MAP
- Pulse pressure: difference between systolic and diastolic
- Rate Pressure Product: heart rate x pulse pressure
- Ambulatory Arterial Stiffness Index (AASI): regression of diastolic pressure against systolic; higher values correspond to stiffer arteries.

- Actigraphy Measurements

NOTE: All measurements listed above display the minimum, hourly mean, maximum, and standard deviation (SD) with the exception of the AASI.

8.2.5.2 The data measurements above is also broken down into asleep/awake readings to have a better understanding of the participant's condition during these two distinct periods.



8.2.5.3 The top-left table shows the total data measurements.
8.2.5.4 The top-right shows the average difference in values between asleep and awake times.
8.2.5.5 The bottom-left and bottom-right tables show the values of the awake measurements and asleep measurements independently from one another.

NOTE: No changes or selections can be made to this view.

8.2.6 Comparison View

PERFORM Centre

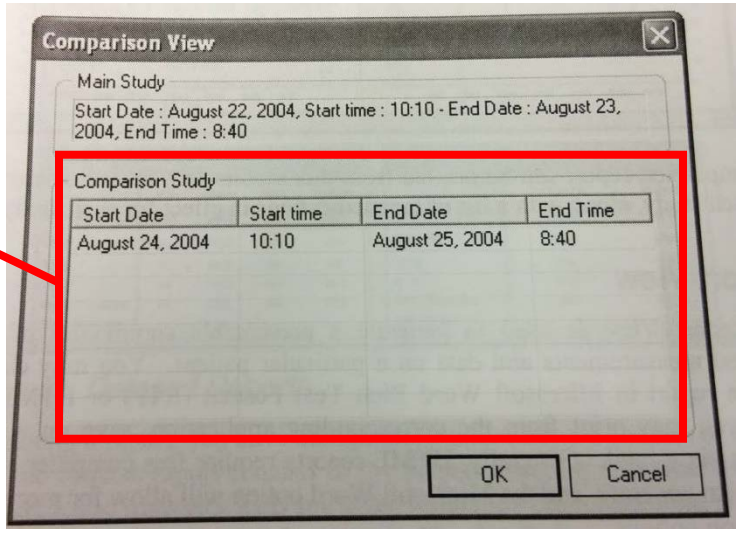
8.2.6.1 Can compare two different ABPM studies and useful for monitoring changes on a participant from one study to another study.

8.2.6.2 Allows for the analyzation of two measurement periods for the following types of measurements:

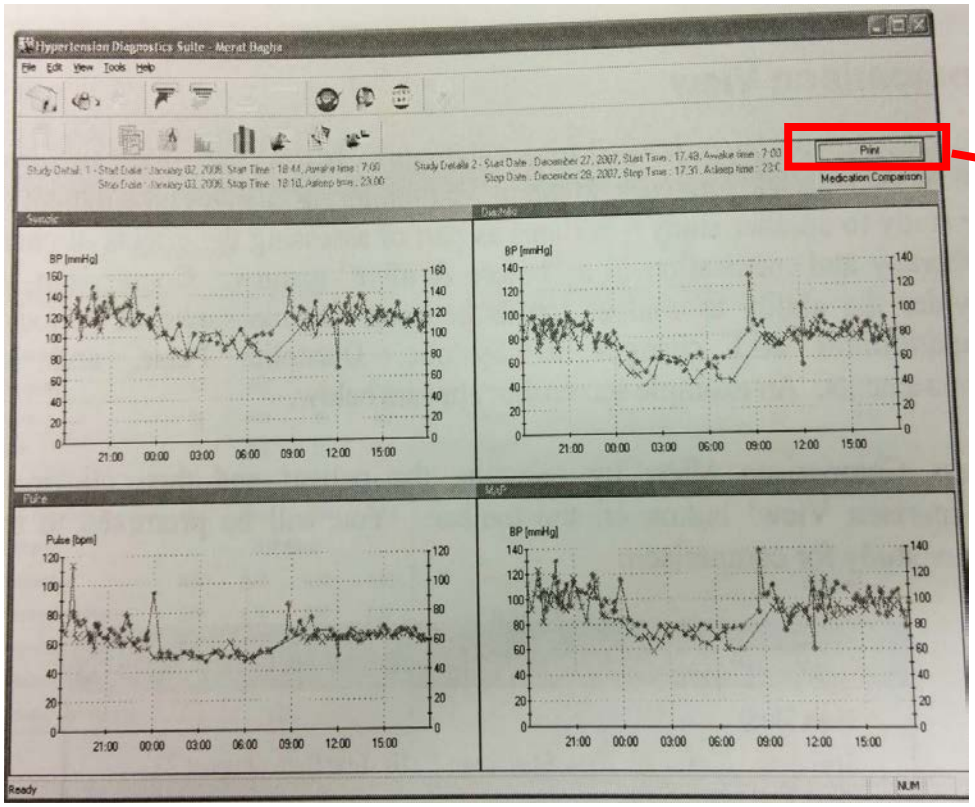
- Systolic BP
- Diastolic BP
- Pulse (Heart Rate)
- MAP

8.2.6.3 To access comparison view, first select the participant and then click on the "Comparison View" button on the toolbar. The following window will open:

List of other studies for comparison



8.2.6.4 The start times of both studies are normalized to the start of the awake cycle (for example, if the main study start time was 7:00 AM and the comparison study start time was 8:00 AM, they would be normalized to period "0". The 24-hour plots are generated from that point onward.)



Can print a copy for each study.

8.2.7 Report View

8.2.7.1 Generates a summary of all collected measurements and data on a particular participant.

8.2.7.2 Can create a Microsoft Word Rich Text Format (RTF) or HTML. Both of these formats can be saved, printed, transmitted via email. You can also save the summary as a PDF.

8.2.7.3 Microsoft Word will enable more flexible file-editing options whereas HTML requires less computer resources and time to generate.

8.2.7.4 If you choose the concise report format, it will consist of the following information:

8.1.1.1.1 Participant data

8.1.1.1.2 Statistical overview

8.1.1.1.3 Diagnostic summary with any additional notes written by the health professional

NOTE: The concise format cannot be altered.

8.2.7.5 The detailed report format consists of more information than the concise report. All of the information can be included or excluded by clicking on the "Report Components" under the Software Configuration menu.

PERFORM Centre

8.2.7.6 These are the following pieces of information that can be included or excluded:

- Blood Pressure Graph
- Tabulated Data
- Histograms
- Medication Information on the Study
- Actigraphy Graph (Accelerometer Data)
- Notes

8.2.7.7 Report Editor

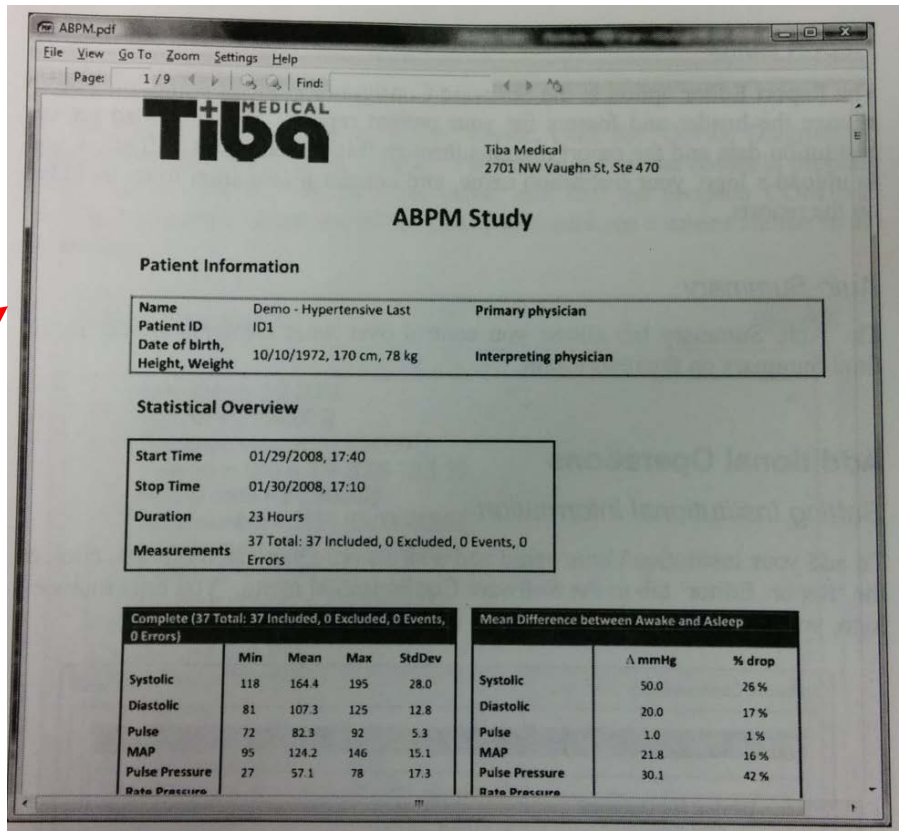
8.2.7.7.1 This option (found in the Software Configuration menu) can do the following:

- Change the headers and footers for your participant report.
- Can include institution data (upload a logo, your institution name, and contact information)
- Adjust the margins

Auto Summary

Under the Auto Summary tab, you can control what will be seen in the final summary on the report form.

Example of a pdf report generated in Adobe Acrobat PDF format.



PERFORM Centre

9 Importing/Exporting Data

9.1 ***Importing Data***

9.1.1 Click on the "Import /Export" icon on the main screen or right click on a folder in the Browse Patients View.
9.1.2 Select the file you wish to import.
9.1.3 Files can only be imported in XML format.

9.2 ***Exporting Data***

9.2.1 Click on the "Import /Export" icon on the main screen or right click on a folder in the Browse Patients View.
9.2.2 Select the file you wish to export.
9.2.3 Files can only be exported in XML format.

NOTE: Basic participant information and blood pressure measurement may be exported into other applications, such as Microsoft Excel.

10 Database Backup

10.1 Under File Menu, click "Backup Database".
10.2 You will need to create a name for the Microsoft Access database file and select/input where it should be saved to.

11 Care & Maintenance

11.1 ***General Care***

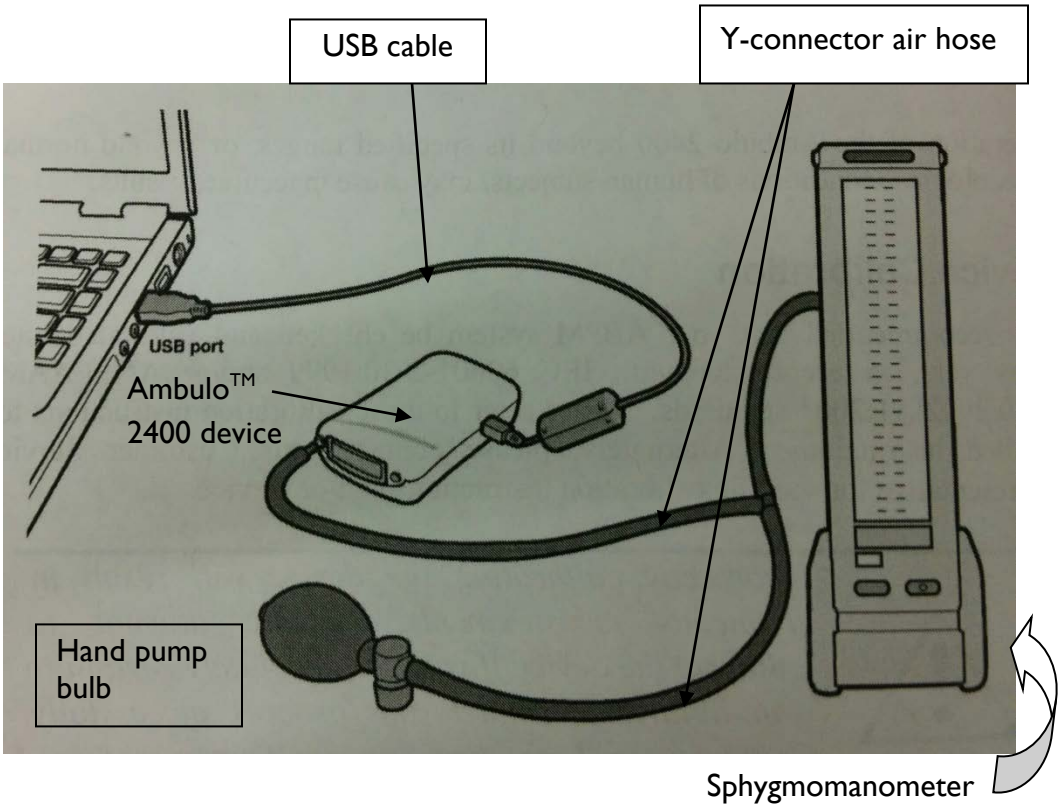
11.1.1 The ABPM device can be cleaned with a soft or damp cloth. Avoid using abrasive cleaning solutions or solvents.
11.1.2 The cuffs can be wiped clean using a mild detergent on a slightly damp cloth or the exterior of the cuff can be hand-washed under running water with a mild detergent.

NOTE: Do not let any water enter the bladder or inside the tubing of the cuffs. Remove any internal bladders and use the Velcro hook/loop fasteners to prevent lint buildup build-up in the hooks.

11.1.3 Remove the batteries when the device is not in use for an extended period of time to preserve battery life.
11.1.4 Do not disassemble the device.
11.1.5 Do not use third-party accessories and parts (such as unsanctioned blood pressure cuffs) with the ABPM system.

11.2 ***Maintenance - Device Calibration***

11.2.1 The ABPM device should be calibrated once every year, in accordance with IEC 60601-2-30:1999 and/or ANSI/AAMI SP10:2002/A1:2003 standards.
11.2.2 Setup equipment as shown below.

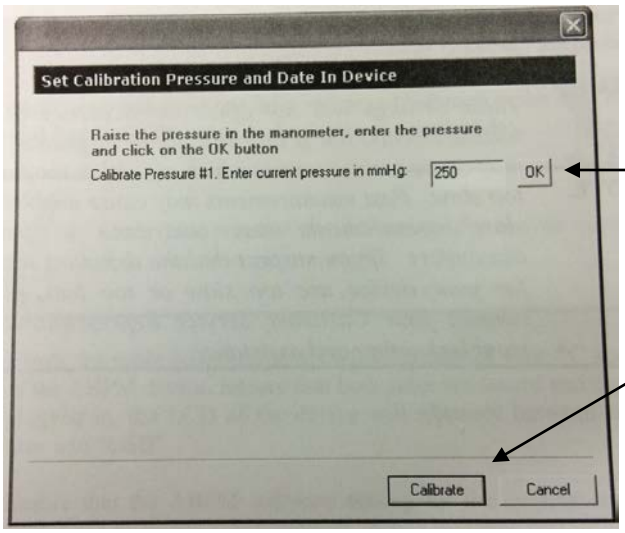


NOTE: The Welch Allyn Propaq simulators can also be used for both calibration and testing of the AmbuloTM 2400. These simulators offer a useful tool for verifying the calibration and accuracy of the Ambulo™ 2400 within its prescribed specifications.

11.2.3 Open "Hypertension Diagnostics Suite" software.
11.2.4 Under Tools menu, select "Calibrate Device".
11.2.5 Indication of two specific pressure points will be asked (e.g. 10 mmHg and 250 mmHg. When asked for these values manually pump (using the hand pump bulb).

11.2.6 Once the pressure has reached the required value, confirm by clicking OK. Do the same procedure for the next value.

11.2.7 When the values are correct, accept the calibration to return to the main menu.



NOTE: The ABPM device has two safety features; the first being that the maximum pressure cannot exceed 285 mmHg (exceeding this value will cause automatic release of all pressure), and second being that the system cannot be above 15mmHg for more than 3 minutes (the device will release all pressure after 3 minutes of greater than 15 mmHg). Both these safety features will cause the calibration process to be reset.

12 Troubleshooting

12.1 ***Power-On Issues***

12.1.1 If LCD does not illuminate or display any characters after the insertion of two fully charged batteries, ensure that they have been placed correctly (at the right polarity).

12.1.2 If the issue persists with the correct configuration of the batteries, contact your Customer Service Representative for further assistance.

12.2 ***Communication Errors***

12.2.1 Make sure the batteries are not depleted and that the LCD screen is displaying the time of day.

12.2.2 Ensure that both sides of the USB cable connections are secure and tight. When plugged, in the device should alternate between current time and "USB".

12.2.3 Ensure that the ABPM software setting for the communication port matches that of your PC. Unplug and then reconnect the USB. If this fails, restart your computer and attempt proceeding instructions again.

12.2.4 If problems persist, contact your Customer Service Representative.

12.3 ***ABPM Device not Functioning***

12.3.1 Connect the ABPM device to your PC via the USB cable. Run the software diagnostic test on the software application to verify if errors are detected.

12.3.2 If no errors are detected, configure the device for use by a participant. Once completed, disconnect the USB cable and press the START/STOP button to initiate a manual measurement.

12.3.3 If the device still fails to take measurements, take note of any error codes displayed on the LCD screen and refer to the Appendix of this POD.

PERFORM Centre

APPENDIX I

Patient Instruction Sheet

- When a blood pressure measurement is in progress, relax your arm and rest it on a flat surface. Minimize any movement for the duration of the measurement. **DO NOT** swing or shake your arm. **AVOID** any tapping, pressure or shock to the cuff as it will affect the measurement accuracy.
- Avoid any kinks, crimping, compression or restriction of the tubes. **DO NOT** puncture or cut the tubes.
- **DO NOT** get the ABPM unit wet or submerge it in liquids. **DO NOT** drop, shake or pound on the ABPM unit. The ABPM system includes expensive and sensitive electronic equipment. You are responsible for the safekeeping of the equipment.
- **DO NOT** remove the batteries from the ABPM unit unless necessary. If the batteries have a low charge, replace them with fully recharged NiMH batteries.
- **DO NOT** attempt to open, disassemble, tamper or repair the ABPM unit.
- **DO NOT** continue to wear the cuff and the unit if you notice rashes or bruises on your arm.
- Pressing the START/STOP button during a measurement will cancel the measurement in progress and deflate the cuff.
- Activate a manual reading by pressing the START/STOP button once if/when you notice any unusual symptoms such as light-headedness or dizziness.
- If you take the cuff off to disrobe, to bathe, or upon the completion of the 24-hour procedure, hold the START/STOP button for three seconds to PAUSE the measurements. If you put the cuff back on your arm and it is connected the ABPM unit, hold the button for three more seconds to disengage the PAUSE function.
- Record the time of measurements as well as any symptoms, conditions, activity, and position on the patient diary. Also take note of meals, snacks, and medications taken. Return the diary to your physician's office along with the ABPM system.

Tiba MEDICAL
Phone: 800-985-TIBA
Web: www.tibamedical.com

ABPM Procedure

Patient Diary

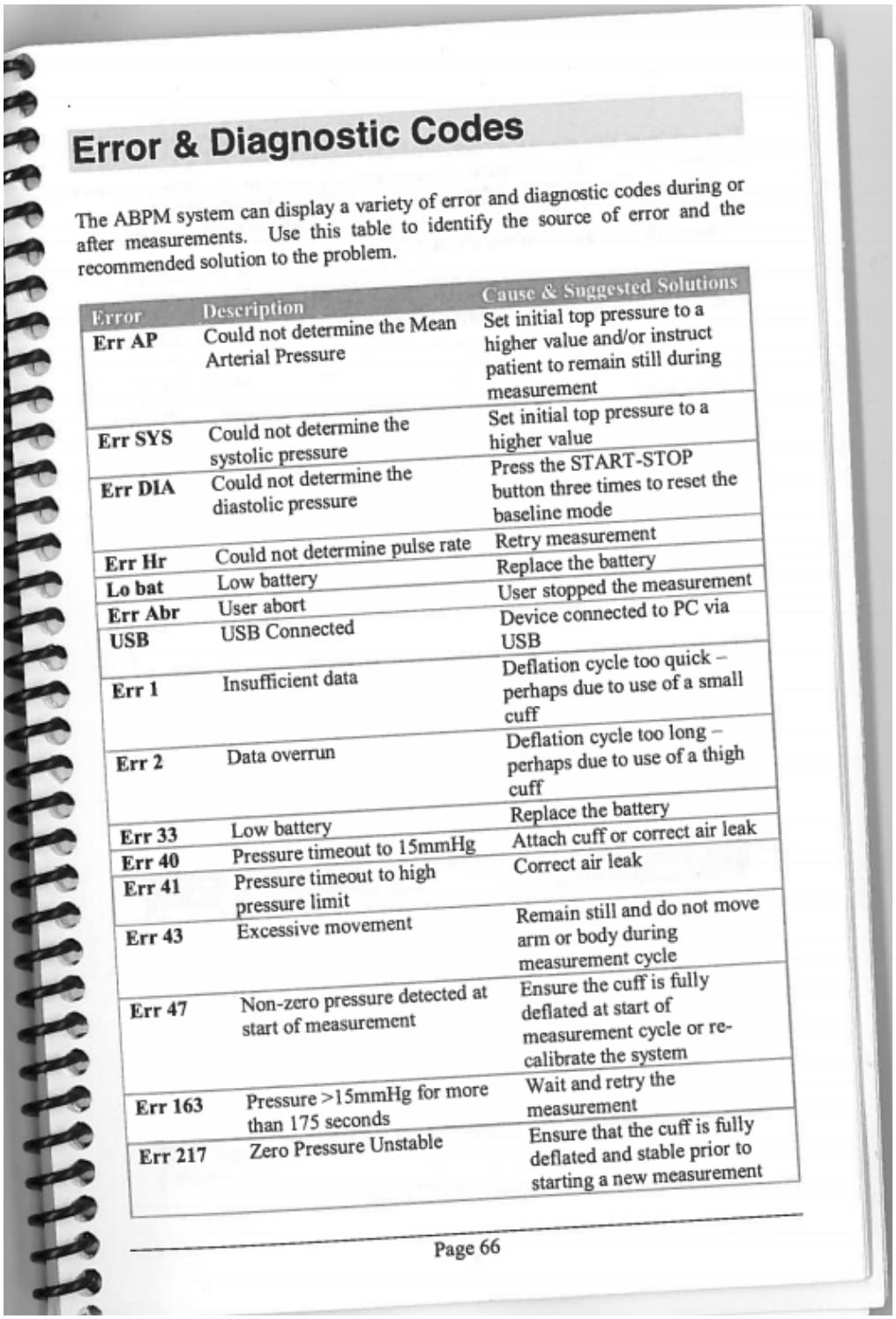
Patient Name:	______________	Date:	______________
Physician:	______________	Nurse:	______________
Clinic Phone:	______________	After Hours:	______________
Day Intervals:	______________	Night Intervals:	______________
Start Time:	______________	Stop Time:	______________
Asleep Time:	______________	Awake Time:	______________

Time	Notes	Time	Notes

PERFORM Centre

APPENDIX II

Error and Diagnostic Codes



Error & Diagnostic Codes

The ABPM system can display a variety of error and diagnostic codes during or after measurements. Use this table to identify the source of error and the recommended solution to the problem.

Error	Description	Cause & Suggested Solutions
Err AP	Could not determine the Mean Arterial Pressure	Set initial top pressure to a higher value and/or instruct patient to remain still during measurement
Err SYS	Could not determine the systolic pressure	Set initial top pressure to a higher value
Err DIA	Could not determine the diastolic pressure	Press the START-STOP button three times to reset the baseline mode
Err Hr	Could not determine pulse rate	Retry measurement
Lo bat	Low battery	Replace the battery
Err Abr	User abort	User stopped the measurement
USB	USB Connected	Device connected to PC via USB
Err 1	Insufficient data	Deflation cycle too quick – perhaps due to use of a small cuff
Err 2	Data overrun	Deflation cycle too long – perhaps due to use of a thigh cuff
Err 33	Low battery	Replace the battery
Err 40	Pressure timeout to 15mmHg	Attach cuff or correct air leak
Err 41	Pressure timeout to high pressure limit	Correct air leak
Err 43	Excessive movement	Remain still and do not move arm or body during measurement cycle
Err 47	Non-zero pressure detected at start of measurement	Ensure the cuff is fully deflated at start of measurement cycle or re-calibrate the system
Err 163	Pressure >15mmHg for more than 175 seconds	Wait and retry the measurement
Err 217	Zero Pressure Unstable	Ensure that the cuff is fully deflated and stable prior to starting a new measurement

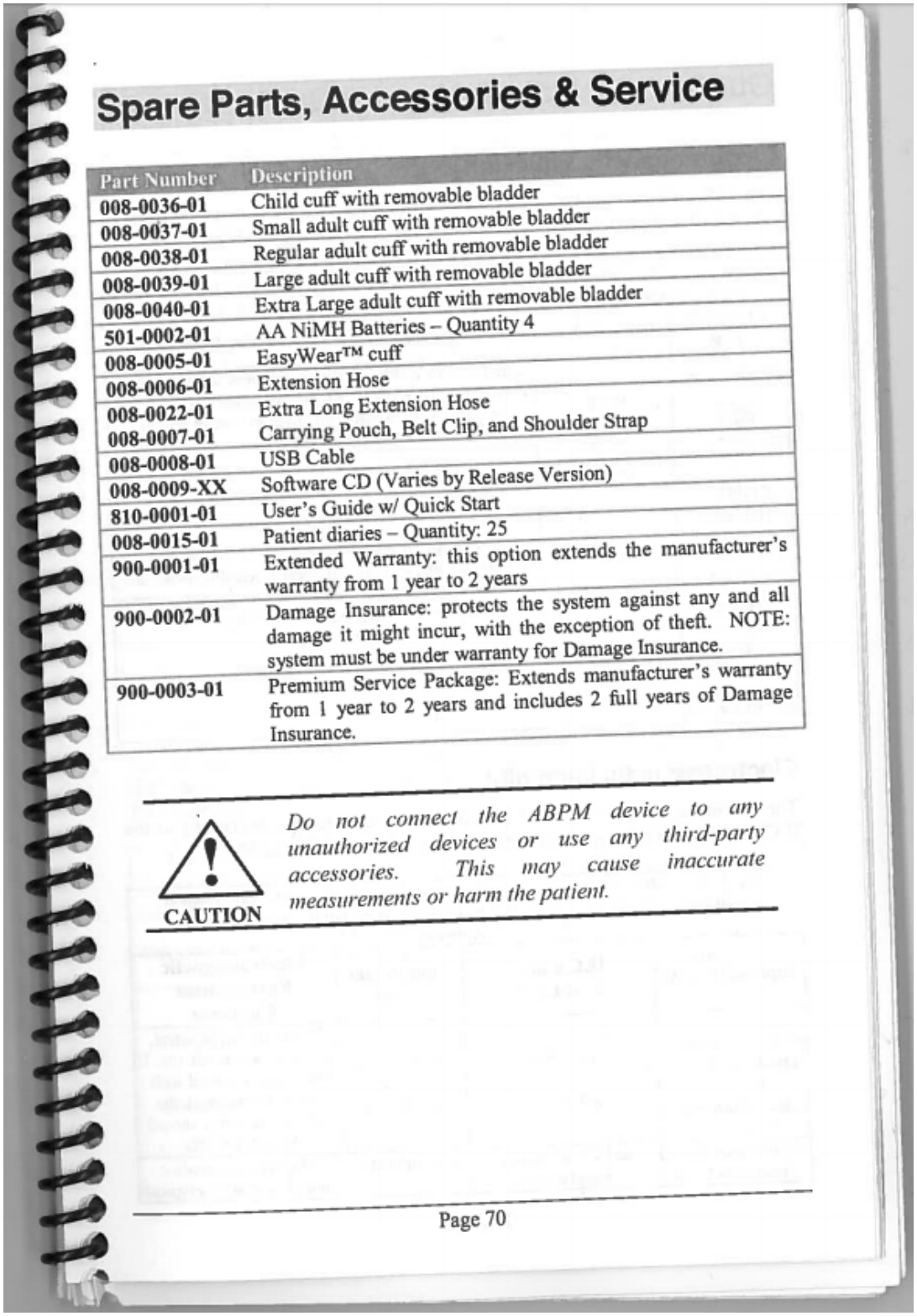
Page 66

Specifications

Physical	
Device Size	119mm × 68mm × 32mm (4.7" x 2.7" x 1.2")
Device Weight	253grams (9 oz.)
Blood Pressure Measurement	
Measurement Principle	Patented oscillometric algorithm with micropump and proportional valve deflation
Measurement Ranges	Systolic 60 to 280 mmHg Diastolic 30 to 160 mmHg Pulse Rate 30 to 180 bpm
Accuracy	Blood Pressure: ±3 mmHg mean difference ±8 mmHg standard deviation Pulse Rate: ±3 bpm According to ANSI/AAMI SP-10:2002 British Hypertension Society; Grade: A/A ISO81060-2
Top Pressure	Default of 180 mmHg User configurable to 285 mmHg
Sample Measurement Intervals	Four adjustable intervals during 24 hour period s each configurable to 0, 5, 10, 15, 20, 30, 45, 60, 90, or 120 minute measurements. Optional randomization factor up to ± 75% within above intervals. Sequential mode for phase I cardiovascular safety trials.
Miscellaneous	
Actigraphy	Recording of 3-axis of motion via accelerometer for display and categorization of sleep/awake cycles via application software
Memory	Solid-state Flash technology. Sufficient for 3000 blood pressure measurements and 7 days of continuous actigraphy
PC Interface	USB 2.0 with mini-B connector Maximum cable length: 1 meter
PC Display	minimum 1024x768 (XGA, or extended VGA)
Electrical	
Battery Type	2 x 1.2V AA batteries Use NiMH batteries only

	Battery charger NOT included	
Battery Capacity	300 measurements using two 2000mAh NiMH batteries	
Voltage & Current	Voltage: 2.4V DC Maximum Current: 610mA Idle Current: 1.3 mA	
Environmental		
Operation	Temperature Humidity Altitude	+5°C to +40°C 30% RH to 95% RH; non-condensing -171m (1034hPa) to +5000m (540hPa)
Storage	Temperature Humidity Altitude	-20°C to +55°C 15% RH to 95% RH, non-condensing -382 m (700hPa) to +5000m (540hPa)
Protection	Type BF Input Protection Defib-Proof IPX-1	
Regulatory Standards		
Safety	EN/IEC 60601-1 EN/IEC 60601-2-30:2000 EN/IEC60601-1-4:1996 AAMI/ANSI SP10:2002 Relevant US Food & Drug Administration guidance & consensus standards as well as 21 CFR 820	
EMC	EN/IEC60601-1-2:2001	
Environmental	IEC 68-2-29 MIL – STD 810E, 1989 ISTA Series 2 AB	

CAUTION *The Ambulo 2400 may not provide accurate results or may be damaged if operated or stored beyond the above specifications. This may also void your warranty coverage.*



Spare Parts, Accessories & Service

Part Number	Description
008-0036-01	Child cuff with removable bladder
008-0037-01	Small adult cuff with removable bladder
008-0038-01	Regular adult cuff with removable bladder
008-0039-01	Large adult cuff with removable bladder
008-0040-01	Extra Large adult cuff with removable bladder
501-0002-01	AA NiMH Batteries – Quantity 4
008-0005-01	EasyWear™ cuff
008-0006-01	Extension Hose
008-0022-01	Extra Long Extension Hose
008-0007-01	Carrying Pouch, Belt Clip, and Shoulder Strap
008-0008-01	USB Cable
008-0009-XX	Software CD (Varies by Release Version)
810-0001-01	User's Guide w/ Quick Start
008-0015-01	Patient diaries – Quantity: 25
900-0001-01	Extended Warranty: this option extends the manufacturer's warranty from 1 year to 2 years
900-0002-01	Damage Insurance: protects the system against any and all damage it might incur, with the exception of theft. NOTE: system must be under warranty for Damage Insurance.
900-0003-01	Premium Service Package: Extends manufacturer's warranty from 1 year to 2 years and includes 2 full years of Damage Insurance.

CAUTION *Do not connect the ABPM device to any unauthorized devices or use any third-party accessories. This may cause inaccurate measurements or harm the patient.*

Page 70

PERFORM Centre

APPENDIX III

POD Training Record Form

PERFORM Centre

POD Title

Use and Cleaning Procedures of Ambulo™ 2400.

POD Code

Ownership	Document type	Area	POD Number	Version
PC	POD	CP	011	01

Training Record

Full Name	
Institution	
Contact (email or phone number)	

Signature

Sign here

Date